UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,012	04/13/2004	Micheal Patrick Dillon	R0130D-CON	4690

24372 7590 04/20/2005

ROCHE PALO ALTO LLC
PATENT LAW DEPT. M/S A2-250
3431 HILLVIEW AVENUE
PALO ALTO, CA 94304

EXAMINER	
STOCKTON, LAURA	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,012	DILLON ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 16, 2004 and February 14, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-62* is/are pending in the application.

4a) Of the above claim(s) *53 and 55-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-52 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

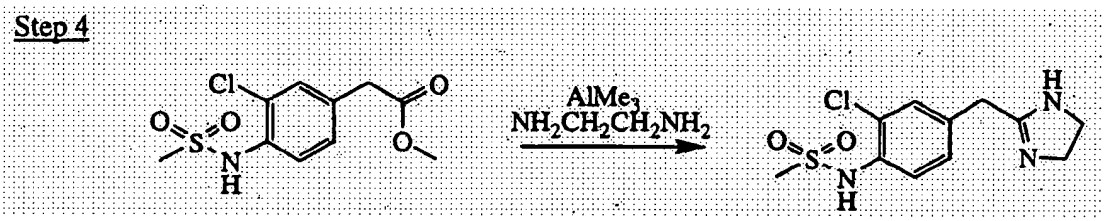
HL

DETAILED ACTION

Claims 48-62 are pending in the application.

Election/Restrictions

Applicants' election without traverse of Group I, and the species of Example 3 in step 4 on page 49 (reproduced below) in the reply filed on December 16, 2004 is acknowledged.



The requirement is still deemed proper and is therefore made FINAL.

Claims 53 and 55-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in the reply filed on

December 16, 2004.

Information Disclosure Statement

The Information Disclosure Statement filed on April 13, 2004 has been considered by the Examiner.

Claim Objections

Claim 54 is objected to because of the following informalities: at the end of line 2 of claim 54, "an" should be changed to "and". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-52 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8, 10, 12-14, 18, 20, 27-30, 32, 44-47, 56-58, 60 and 64 of U.S. Patent No. 5,952,362 (Cournoyer et al.) and claims 1-10, 17 and 26-39 of U.S. Patent No. 6,756,395 (Dillon et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in the claims of U.S. Patent No.

6,756,395 and are positional isomers of the compounds claimed in U.S. Patent No. 5,952,362.

In U.S. Patent No. 6,756,395, see claim 1 (column 62) and especially the first compound listed in claim 38 (column 65) of this patent which is the same as the first compound listed in instant claim 52.

In U.S. Patent No. 5,952,362, see claim 1 (columns 124-125) and especially claim 27 (column 127) and claim 44 (column 128). The sulfonamide group in the compounds found in U.S. Patent No. 5,952,362 is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer). Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as claimed in U.S. Patent No. 5,952,362 since such structurally related compounds suggest one another and would be expected to share common properties absent

a showing of unexpected results. *In re Norris,* 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare compounds embraced by the claims of U.S. Patent No. 6,756,395, or alternatively, prepare positional isomers of the compounds claimed in U.S. Patent No. 5,952,362, to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought

> to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Cournoyer et al. {U.S. Pat. 5,952,362} for reasons set forth below.

The applied reference has a common inventor (i.e., Counde O'Yang) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or

declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournoyer et al. {U.S. Pat. 5,952,362}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim imidazolin-2-yl-methylphenyl compounds. Cournoyer et al. teach imidazolin-2-yl-methylphenyl compounds that are structurally similar to the instant claimed compounds. See in Cournoyer et

al., for example, formula 1 in columns 7 and 8 and especially the sixth compound listed in the table in column 39.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of Cournoyer et al. and the compounds instantly claimed is that the sulfonamide group is attached to the phenyl ring *meta* to the imidazolin-2-yl-methyl group instead of *para* to the imidazolin-2-yl-methyl group as instantly claimed (i.e., a positional isomer).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Cournoyer et al., since such structurally related compounds suggest one another and would be

expected to share common properties absent a showing of unexpected results. *In re Norris,* 84 USPQ 458 (1950).

One skilled in the art would thus be motivated to prepare positional isomers of the compounds taught by Cournoyer et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would be useful in treating, for example, urinary incontinence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either

Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

April 14, 2005

JOSEPH K. McKANE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600